



The L300[®] Plus System



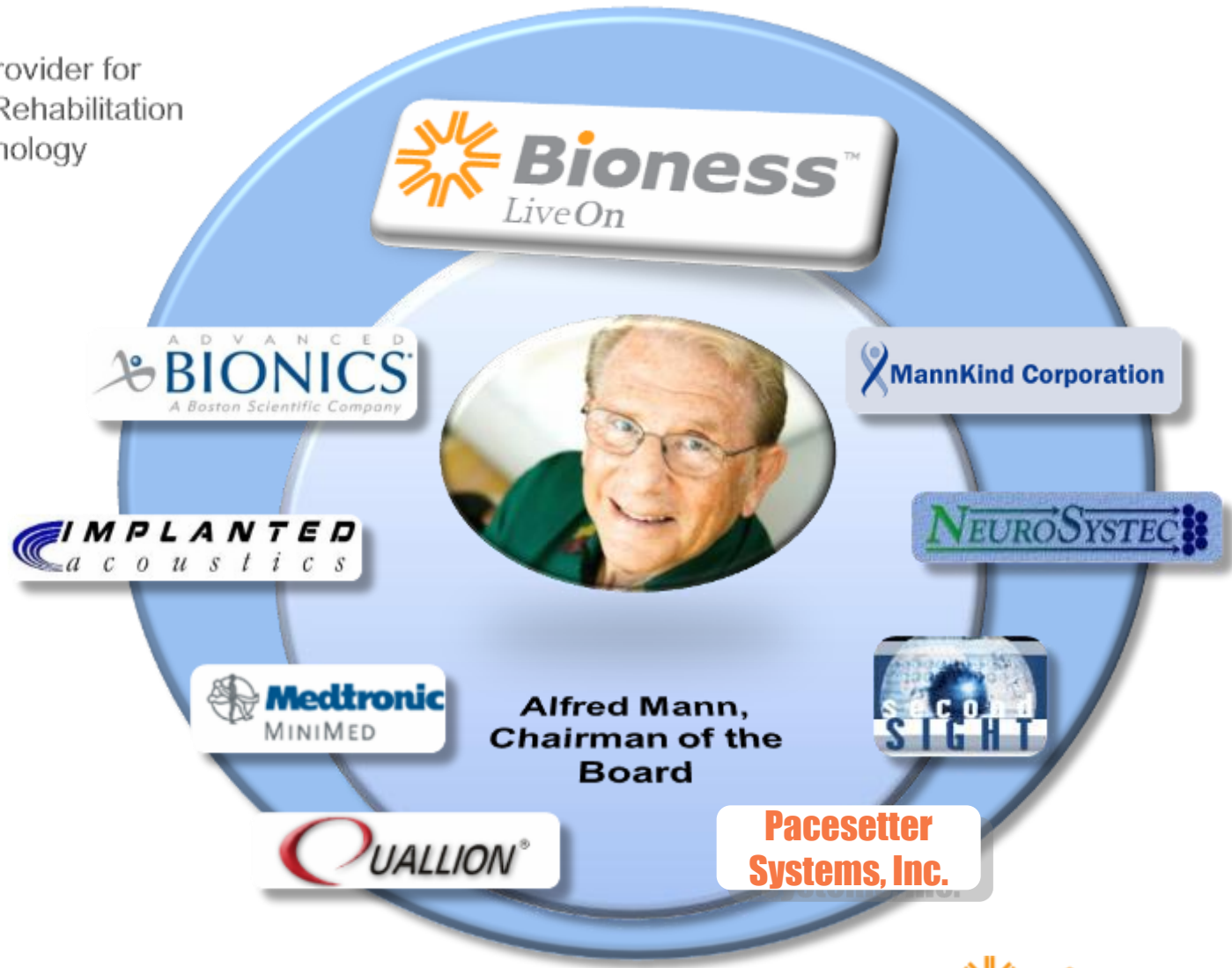
Objectives

- Introduction to Bioness
- Introduce Large Electrodes, L300 Systems
- Introduce the L300 Plus System
 - Background
 - Features
 - Value
 - Pilot Research Finding
- Discuss Next Steps:
Introduction Day



Bioness® is an Alfred Mann Company

A medical solutions provider for
Physical Medicine & Rehabilitation
using innovative technology



Bioness Neuromodulation Technology

EXOSKELETAL

IMPLANTABLES

technology



H200®



L300®



L300 Plus™



H200® Wireless



Microstimulators

2004 - 2010

2006+

2011+

future

Bioness Rehabilitation Technology



Complete Gait Systems



February 2010+

Gait Dysfunction and Rehabilitation

Connections with Ambulation Status:

- Disability
- Discharge
- Falls Risk
- Wellbeing
- Socialization
- Vocation
- Goals



FES Support and Development



- Recommend treatment with FES for stroke patients with impaired muscle contraction.
- Recommend FES for gait training post stroke
- L300 is endorsed by APTA
- Supportive evidence base has expanded in all major neurologic pathologies; i.e. CVA, SCI, MS, CP
- Reimbursement Improving
- Technology continues to progress

The Large Cloth Electrode, L300 Systems



Simplify the Fitting Process

- Large Size Cloth-Based Electrode
- Simplifies fitting, greatly reduces set-up (no fitting cables)
- Improves Recruitment
- Increases Comfort
- “Snap and Go”
- Available for L300 and L300 Plus Systems



L300 Large Electrodes



L300 Plus System



Challenges of Neurologic Gait

- Usually Involves Several Joints/Muscle Groups
- Complicated by Impairment in Timing, Control, and Sensation
- Difficulties in Stance and Swing
- Common impairments can present in different patterns



Challenges of Neurologic Gait

- Solutions often fall short and compensatory in nature
- No “one” solution works for everyone
- Proximal control difficult to address
- Compensation patterns develop early



L300 Plus System: Design Concept Example



Without Stimulation



With Stimulation

Stimulation of Hamstrings During Stance

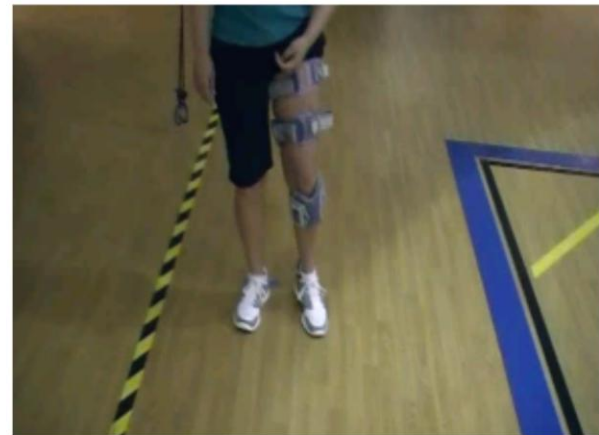
L300 Plus System: Select Design Achievements

- Addresses Dysfunction of Hamstrings and Quadriceps and Associated Gait/Functional Deficits
- Clinic and Home Use Value
- Provide Therapeutic and Orthotic Benefit
- Easy to Apply
- Synchronized to L300
- Fully Customized Gait Setting (Stance and Swing)



L300 Plus System: Potential Impact on Gait

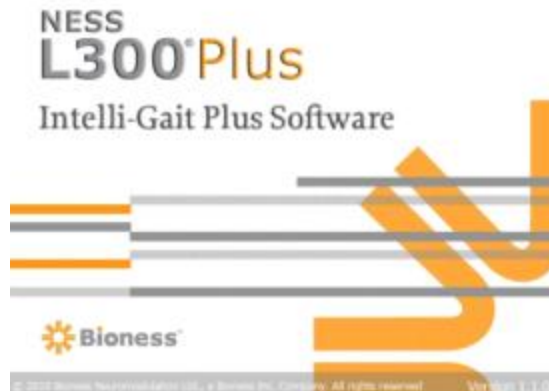
- Better Knee Control
- Increased Step Length
- Increased Stance Time
- Better Swing Clearance
- Improved Symmetry
- Increased Walking Speed
- Decreased Energy Expenditure



First Session with L300 Plus

L300 Plus System Components

- New components include the Thigh Cuff with Stimulator and multi-function Control Unit
- Uses existing L300 Cuff and Gait Sensor
- Can be acquired as a System or Upgrade existing L300
- Specific software added to PDA via SD card



Thigh Functional Stimulation Cuff

- Elongation bar and adjustable straps for length and girth tuning
- 12 “Quick fit” combinations of thigh electrode positions
- Reproducible electrode placement
- Unique Cloth electrodes for comfort



Thigh Functional Stimulation Cuff

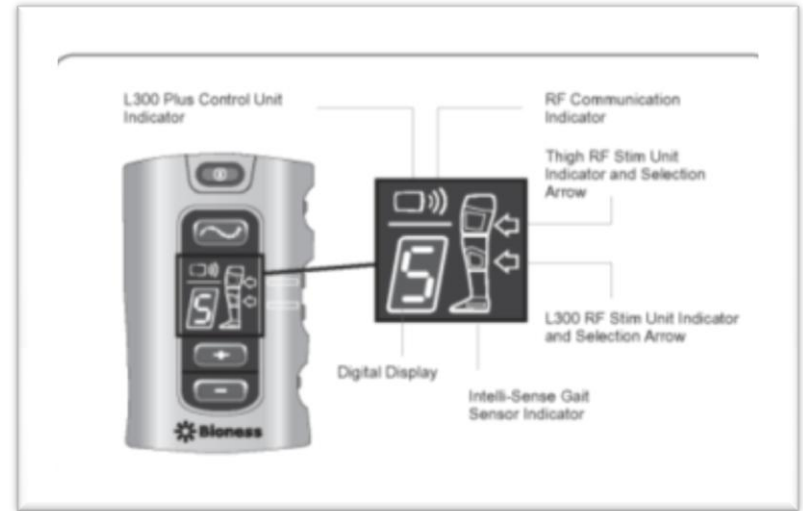
- Position on Thigh for Quads versus Hamstrings
- Anatomical landmarks ensure accurate electrode placement
- Comfortable “closed” cell materials allow for easy clinic cleaning
- Can be donned easily
- Holds rechargeable stimulation unit
- Right and Left Specific



L300 Plus Control Unit

Control Unit

- One Control Unit Runs the L300 Plus System
- Independent Control of L300
- Existing L300's Upgradable
- Updated Features and Electronics



L300 Plus Control Unit

Control Unit

- Allows you to toggle between L300 Cuff and Thigh Cuff
- Independent operation of stimulation for testing, training mode and clinician's mode
- Activate Audio Feedback for Cueing
- Fine Tuning for Home Use



L300 Plus Clinic Value

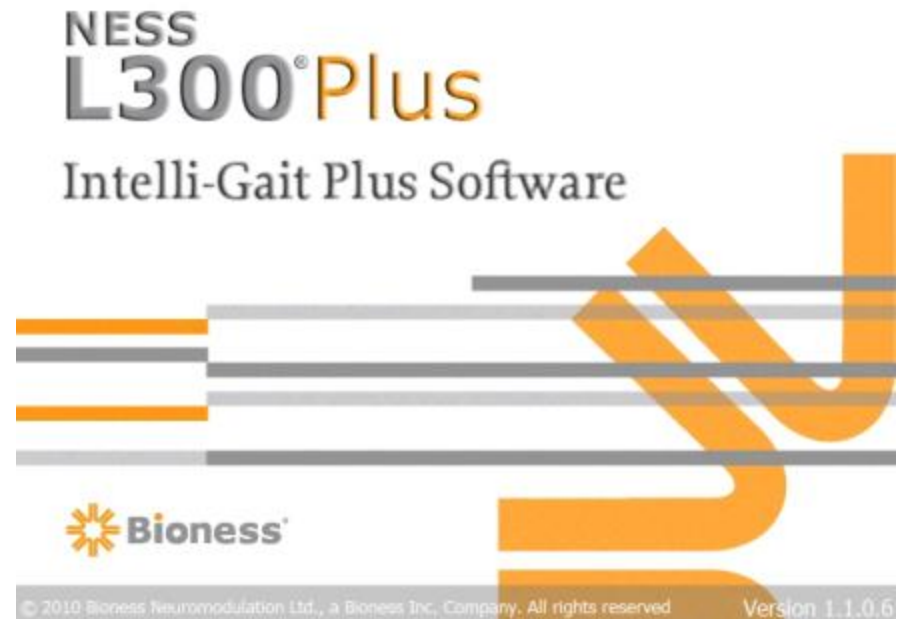
- Allows for Early Activation of Key Muscle Groups
- Aids in Pre-gait Activity and Early Function
- On-Demand Stimulation Control or Sensor Activated allows for easy integration
- Adjunct to other Interventions e.g. BWSLT



Intelli-Gait Plus Software

Software

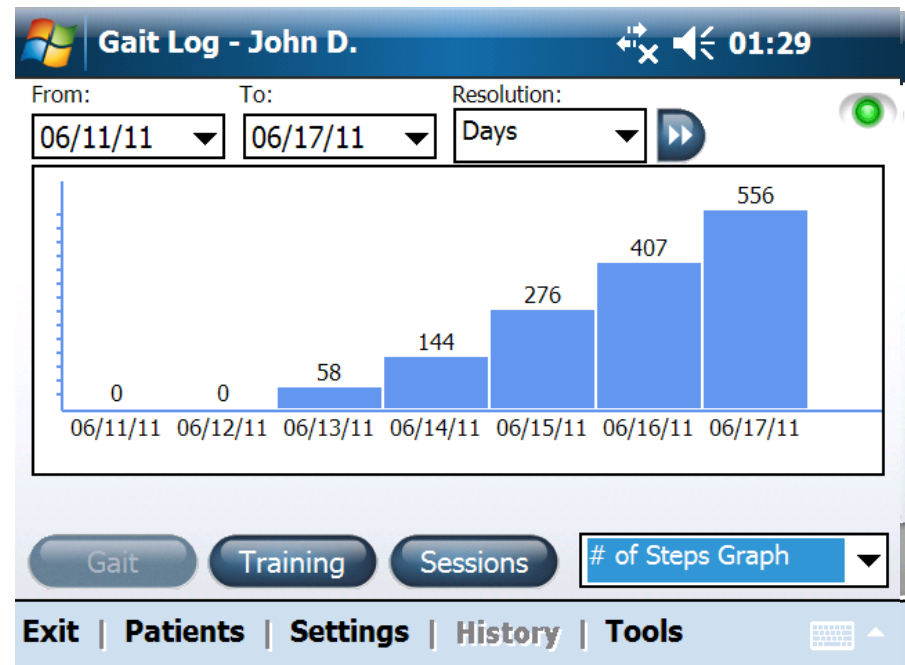
- Wireless Programming of the Thigh Cuff and L300
- Information Icons and auto trouble shooting
- Auto upgrade of older L300 Systems



Intelli-Gait Plus Software

Software

- Choose Muscle group(s)
- Set Stimulation Independently
- Real Time Adjustment for Customized Gait
- Set Training
- Track Progress



L300 Plus Videos



- Provides Immediate Orthotic Benefit
- Addresses issues in Swing and Stance
 - Therapeutic Impact of FES

L300 Plus Videos

No Stimulation



L300 Plus



L300 Plus Feasibility Study

Subjects:

- Forty-five (45) subjects suffering from foot drop and thigh muscles weakness ($<4/5$) due to upper motor neuron (UMN) injury or disease.

Primary objective:

- Evaluation of the safety of the NESS L300 Plus System in patients following an UMN injury or disease.

Secondary objectives:

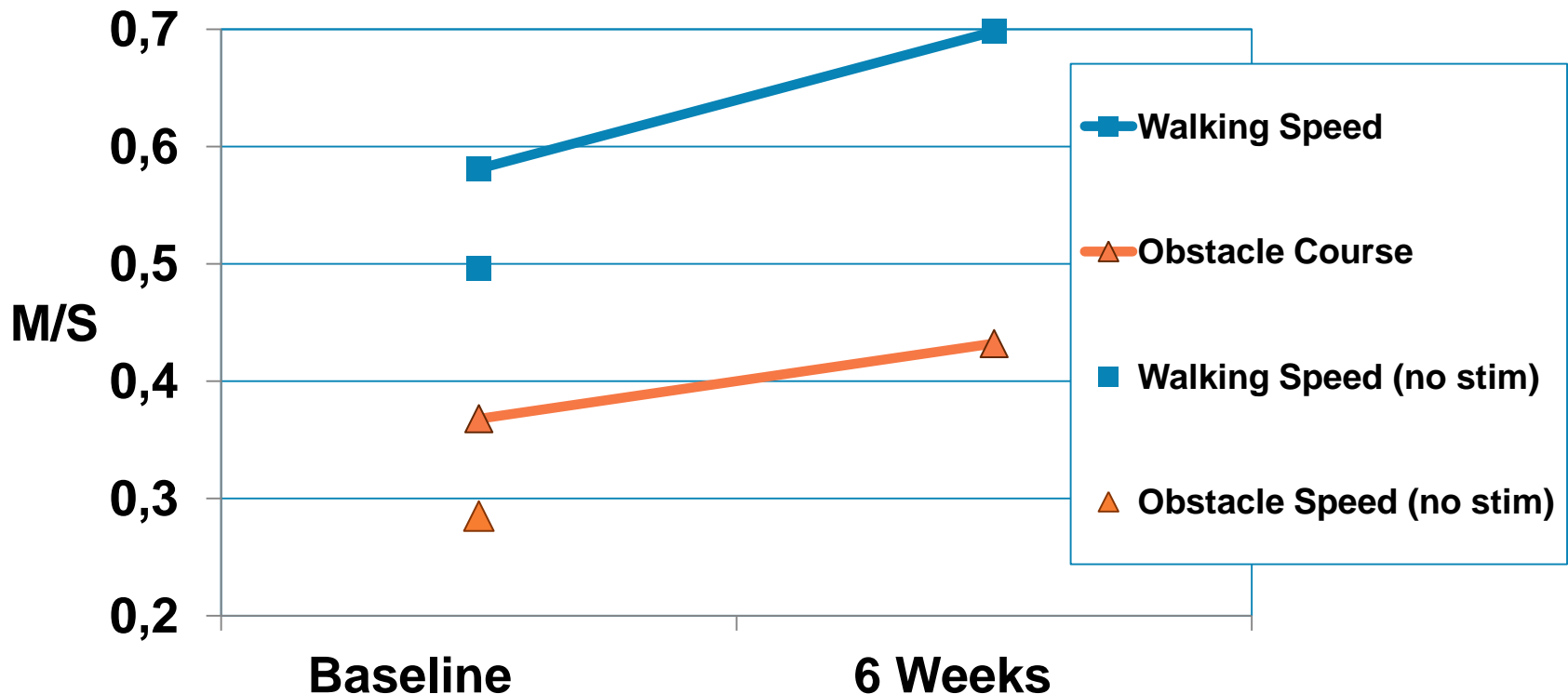
- Obtaining information about the performance of the NESS L300 Plus System as a gait assistive device.
- Evaluation of the clinical benefits of the NESS L300 Plus System.

L300 Plus Feasibility Study

- The study protocol duration for each subject was six weeks.
- Case Series Trial (Pre-post prospective design)
- Investigate the impact of adding thigh stimulation to L300 System
- Gait performance outcomes included:
 - Walking Speed
 - Obstacle Course Speed
 - Gait Asymmetry Index
 - Single Limb Support

L300 Plus Feasibility Study: Gait Speed

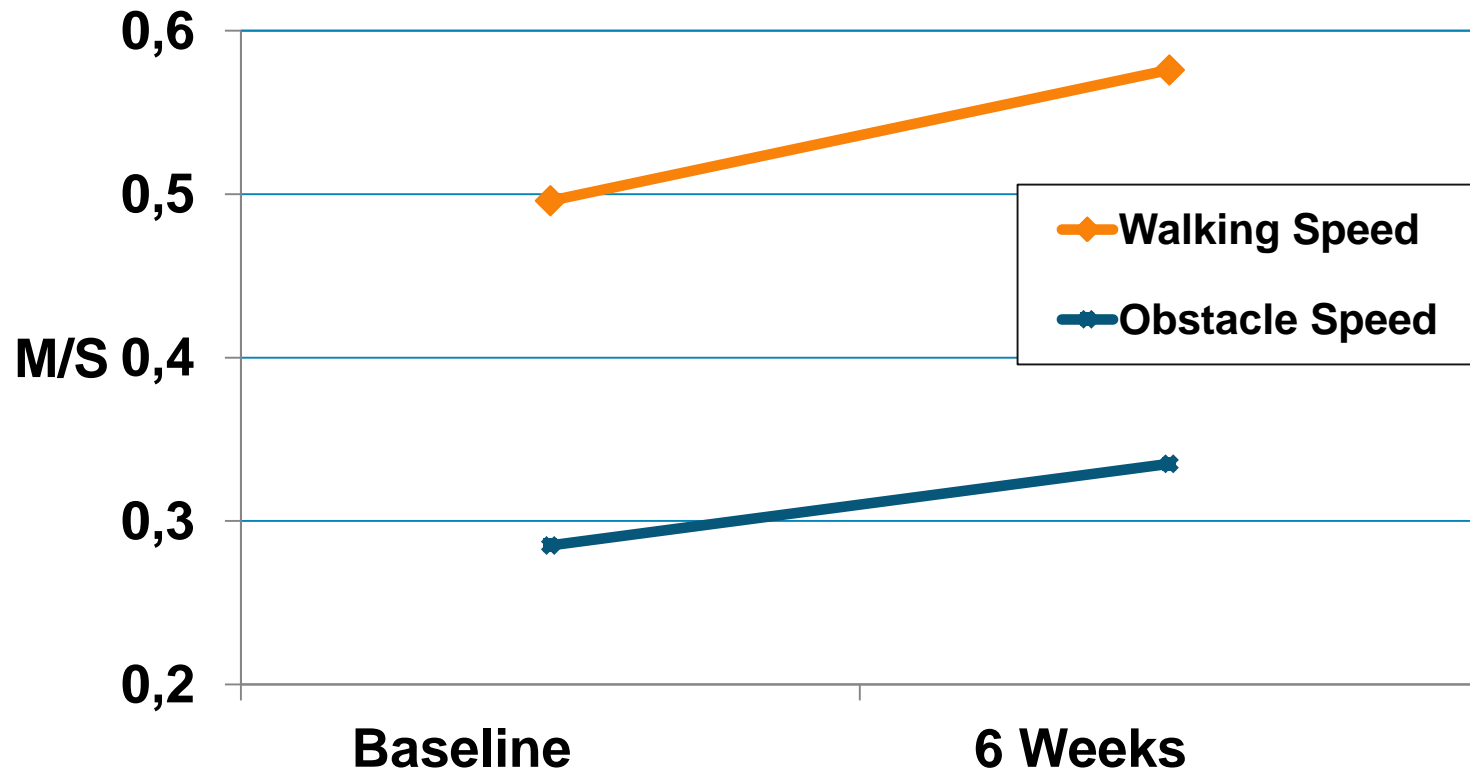
L300 Plus Orthotic Effect



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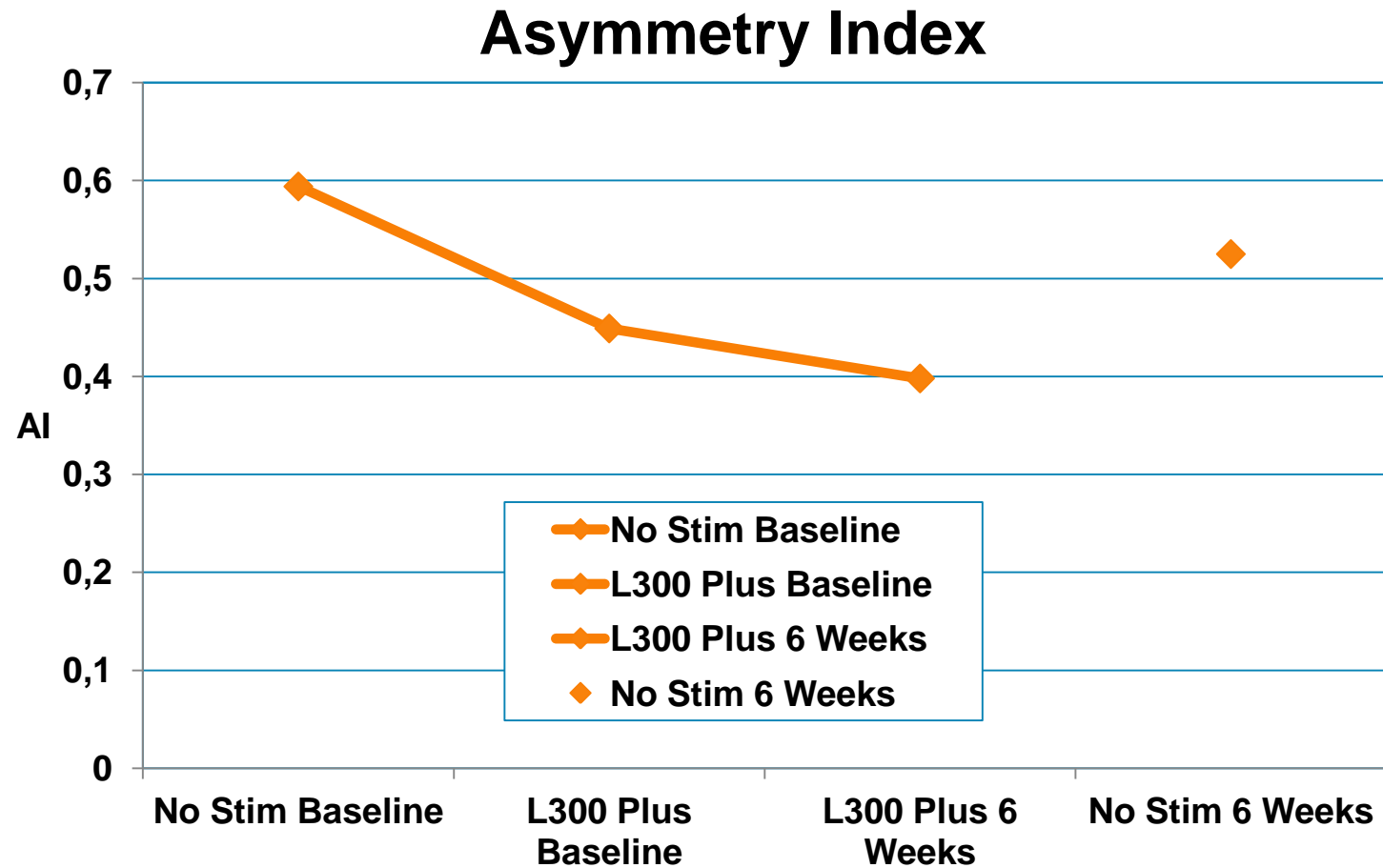
L300 Plus Feasibility Study: Gait Speed

L300 Plus Therapeutic Effect



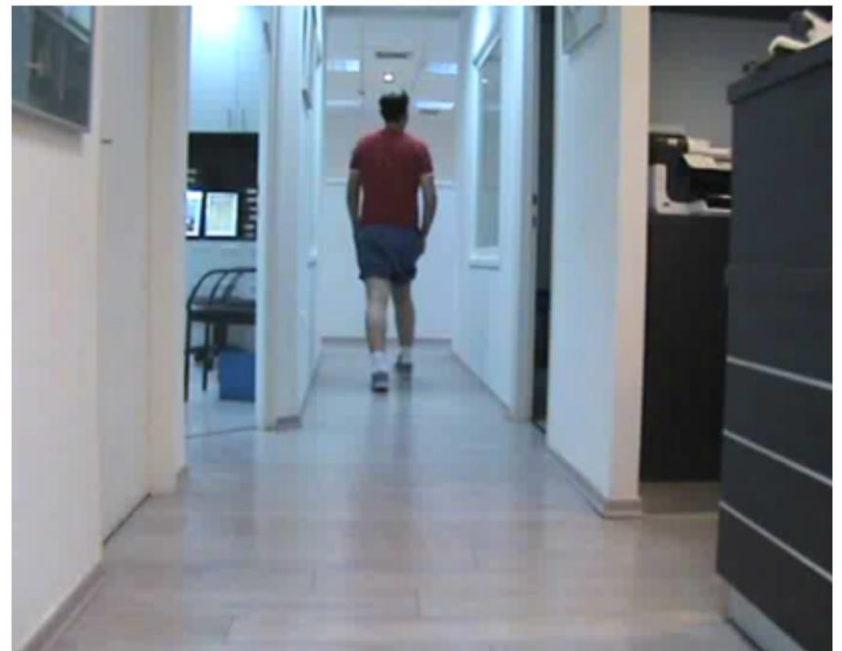
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L300 Plus Feasibility Study: Symmetry



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L300 Plus Feasibility Study: Outcome



Knee Hyperextension exacerbated with speed

L300 Plus Feasibility Study: Outcome



L300 Plus at Comfortable Pace: HS in Stance/Preswing

L300 Plus Feasibility Study: Fast Pace



Fast Pace No Stimulation

L300 Plus Feasibility Study: Fast Pace



L300 Plus at Fast Pace: HS in Stance/Pre-swing

Feasibility Study Summary

- Clinical need for knee control following UMN disorder is evident
- Current technology is limited, mainly compensatory, and poorly accepted
- FES can provide a viable “hybrid” solution
- User satisfaction and acceptance is favorable
- Designing an FES system for knee control is warranted

L300 Plus Features Review

- Wireless Communication
- Operates off the same Clinician's Programmer as the L300
- Reversible thigh cuff for quadriceps or hamstrings
- Single control unit operation
- Leverages the L300 technology platform to provide a full paretic extremity gait solution
- Utilizes Large Cloth Electrodes

